

# Notice of Allowability

Application No.

09/500,904

Examiner

Bao Qun Li

Applicant(s)

HARLEY ET AL.

Art Unit

1648

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Oct. 21, 2004.
2. ☒ The allowed claim(s) is/are 6 and 19.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 02/05/2004
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date March 29, 2007.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

Bao Qun Li

## **EXAMINER'S AMENDMENT**

### **Response to the amendment**

The amendment filed on April 05, 2004 have been entered.

Claims 6, 7, 8, have been amended. Claims 1-5, 11-18 and 23-26 have been canceled. Claims 6-10, 19-22 are pending and considered.

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Steven J. Highlander on March 28-29, 2007.

The application has been amended as follows:

Claim 6 (current amended)

In line 1 after "diagnostic" please delete the citation from "test" to the citation in line 7 before "PPGRRP" and insert --- reagents for determining whether an individual has or may develop Epstein Barr Virus (EBV)-induced systemic lupus erythematosus (SLE) comprising (a) peptide antigens, which can be used to detect antibodies recognizing the Epstein-Barr virus antigen epitopes including ----

In line 7 after "(SEQ ID NO: 3), please delete  
"GAGAGAGAGAGAGAGAGAGAGAGA (SEQ ID NO:7),"

In line 18 after "(SEQ ID NO: 50)" please delete "or the peptide consisting or " and insert --- and ---

In 19 after "(SEQ ID NO: 98)" please delete "antibodies reactive with these peptides"

In line 21 after "samples" please delete rest of citation and insert --- obtained from individuals with EBV infection but without evidence of SLE. ----

Claim 6 (re-iterated) Diagnostic reagents for determining whether an individual has or may develop Epstein Barr Virus (EBV)-induced systemic lupus erythematosus (SLE) comprising (a) peptide antigens, which can be used to detect antibodies recognizing the Epstein-Barr virus

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antigen epitopes including PPPGRRP (SEQ ID NO: 1), GRGRGRGG (SEQ ID NO:2), RGRGREK (SEQ ID NO:3), GGSGSGPRHRDGVRRPQKRP (SEQ ID NO:25), RPQKRPSC (SEQ ID NO:26), QKRPSCIGCKGTHGGTG (SEQ ID NO:27), GTGAGAGARGRGG (SEQ ID NO:99), SGGRGRGG (SEQ ID NO: 100), RGGS GGRRGRGR (SEQ ID NO: 101 ), RARGRGRGRGEKRPRS (SEQ ID NO:102), SSSSGSPRRPPPGR (SEQ ID NO:103), RPPPGRRPFFHPVGEADYFEYHQEG (SEQ ID NO:104), PDVPPGAI (SEQ ID NO:33), PGAIEQGPA (SEQ ID NO:34), GPSTGPRG (SEQ ID NO:105), GQGDGGRRK (SEQ ID NO:37) DGGRRKKGGWFGKHR (SEQ ID NO:38), GKHRGQGGSN (SEQ ID NO:106), GQGGSNPK (SEQ ID NO: 107), NPKFENIA (SEQ ID NO: 108), RSHVERTT (SEQ ID NO:109), VFVYGGSKT (SEQ ID NO:110), GSKTSLYNL (SEQ ID NO: 111), GMAPGPGP (SEQ ID NO:46), PQGPLRE (SEQ ID NO:47), CNIRVTVC (SEQ ID NO:48), RVTVC SFDDG (SEQ ID NO:49), PPWFPPMVEG (SEQ ID NO:50) and GPQRRGGDNHGRGRGRGRGRGGGRPG (SEQ ID NO:98); and (b) control samples obtained from individuals with EBV infection but without evidence of SLE.

Claim 19 (current amended). In line 1 after “determining” please delete rest of citations in the claim and insert --- that an individual has or may develop EBV-induced SLE comprising:

- a) mixing a test sample with the diagnostic reagents of claim 6,
- b) analyzing antibodies binding to the peptides antigens of the EBV antigen epitopes of claim 6,
- c) comparing the results obtained with control samples from individuals infected with Epstein-Barr virus but without evidence of SLE, and
- d) determining if levels of antibodies binding to each of the peptides antigens in the test sample is at least three standard deviations greater than the normal means of the levels of antibodies binding in the control samples, which indicates the individual has or may develop EBV-induced SLE. ----

Claim 19 (re-iterated) A method for determining that an individual has or may develop EBV-induced SLE comprising:

- a) mixing a test sample with the diagnostic reagents of claim 6,

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- b) analyzing antibodies binding to the peptides antigens of the EBV antigen epitopes of claim 6,
- c) comparing the results obtained with control samples from individuals infected with Epstein-Barr virus but without evidence of SLE, and
- d) determining if levels of antibodies binding to each of the peptides antigens in the test sample are at least three standard deviations greater than the normal means of the levels of antibodies binding in the control samples, which indicates the individual has or may develop EBV-induced SLE.

Please cancel claims 7-10, and 20-22.

Claims 6 and 19 are allowed.

2. The following is an examiner's statement of reasons for allowance: The priority of claims 6 and 19 is considered to the effective filing date of the parental application 08/781,296. No prior art teaches or suggests that a group of EBV antigen epitopes cited in claim 6 are cross-reactive with the antigens epitopes of SLE, which can be detected with a significant higher binding activities in a patient infected with EBV when the individual has or may develop EBV induced SLE.

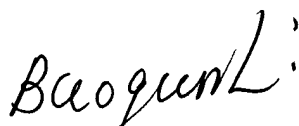
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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March 29, 2007



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